

§ 520.1616

ulcers, 0.9 mg/lb of body weight (2 mg/kg) once daily for at least an additional 4 weeks.

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for 8 or 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

(2) *Indications for use.* (i) For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(ii) For prevention of gastric ulcers in horses.

(3) *Limitations.* Do not use in horses intended for human consumption.

[69 FR 13220, Mar. 22, 2004, as amended at 71 FR 59374, Oct. 10, 2006]

§ 520.1616 Orbifloxacin tablets.

(a) *Specifications.* Each tablet contains 5.7, 22.7, or 68 milligrams (mg) orbifloxacin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*(1) *Amount.* 2.5 to 7.5 mg per kilogram body weight once daily.

(2) *Indications for use.* For management of diseases associated with bacteria susceptible to orbifloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food producing animals.

[71 FR 14643, Mar. 23, 2006, as amended at 75 FR 26646, May 12, 2010]

§ 520.1618 Orbifloxacin suspension.

(a) *Specifications.* Each milliliter of suspension contains 30 milligrams (mg) orbifloxacin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

(d) *Conditions of use—*(1) *Dogs—*(i) *Amount.* 1.1 to 3.4 mg/lb (2.5 to 7.5 mg/kg) of body weight once daily.

(ii) *Indications for use.* For the treatment of urinary tract infections (cystitis) in dogs caused by susceptible strains of *Staphylococcus*

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pseudintermedius, *Proteus mirabilis*, *Escherichia coli*, and *Enterococcus faecalis* and skin and soft tissue infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, coagulase-positive staphylococci, *Pasteurella multocida*, *Proteus mirabilis*, *Pseudomonas* spp., *Klebsiella pneumoniae*, *E. coli*, *Enterobacter* spp., *Citrobacter* spp., *E. faecalis*, β -hemolytic streptococci (Group G), and *Streptococcus equisimilis*.

(2) *Cats—*(i) *Amount.* 3.4 mg/lb (7.5 mg/kg) of body weight once daily.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *S. aureus*, *E. coli*, and *P. multocida*.

[75 FR 26646, May 12, 2010]

§ 520.1628 Oxfendazole powder and pellets.

(a) *Specifications—*(1) *Powder for suspension.* Each gram of powder contains 7.57 percent oxfendazole.

(2) *Pellets.* Each gram of pellets contains 6.49 percent oxfendazole.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* 10 milligrams per kilogram of body weight.

(2) *Indications for use.* The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and immature pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *Strongylus vulgaris*, and *Strongylus equinus*), and small strongyles.

(3) *Limitations—*(i) *Powder for suspension.* For gravity administration via stomach tube or for positive administration via stomach tube and dose syringe. Discard unused portions of suspension after 24 hours. Mix drug according to directions prior to use. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Pellets.* The drug is given by sprinkling on the grain portion of the ration. Withholding feed or water prior